Hydroxychloroquine as Post-Exposure Prophylaxis Against COVID-19 Infection (PEPCOH)

NCT04372017

Informed Consent Document

Continuing Review Date 03.11.2021

Sanford Health Consent and HIPAA Authorization to Participate in a Research Study

Study Title:	Post-Exposure Prophylaxis for COVID-19 with Hydroxychloroquine (PEPCOH)
Sponsor:	Sanford Health
Principal Investigator:	Susan Hoover, MD, PhD
Site Name:	Sanford Health Sioux Falls, SD

You are being asked to take part in a research study sponsored by Sanford Health. Dr. Susan Hoover is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are other individuals who are part of the research team.

OVERVIEW AND KEY INFORMATION

Research is the process of solving problems and finding facts in an organized way. The information below will give you key information to help you decide why you may or may not want to be in the research study.

Please read this document carefully and do not hesitate to ask questions about this information and ask the study staff to explain the words or information that you do not understand. You should not join this research study until all of your questions are answered.

- **Voluntary.** Participation is voluntary, meaning that you may choose not to take part or you may choose to leave the research study (withdraw) at any time without loss of benefits. Your decision whether or not to participate will not affect your current of future relations with Sanford Health.
- **Purpose.** The purpose of this study is to see if hydroxychloroquine will reduce the chances of developing a COVID-19 infection after a high-risk exposure. Hydroxychloroquine is not FDA approved to treat or prevent COVID 19 and it is an experimental drug for this research.

  Participation. The length of your participation will be 12 months: 5 days of treatment with hydroxychloroquine or placebo with follow-up phone calls at day 3, day 5, day 14, day 35 and 12 months.

  Risks. There are potential risks with this research study. The primary risk is related to the study drug. Common side effects include nausea, vomiting, diarrhea and loss of appetite. More serious side effects such as cardiac effects, vision damage, muscle damage, nerve damage, suicidal behavior, low blood sugar and skin effects. These risks will be explained in more detail later in this document. The study team will review your medications and medical history to make sure you are not at an increased risk of side effects.

  Confidentiality. There is the risk of a breach of confidentiality, the unexpected release of your personal health information. While we cannot guarantee absolute confidentiality, we will use all available security measures to minimize the risk that this information is given to someone who is not involved in the study.

In addition to the risks described, there may be unforeseen risks with this research that may hurt you in ways that are currently unknown.

- **Benefits.** You may or may not benefit from this study. It is currently unknown whether or not hydroxychloroquine will prevent the development of COVID-19 following an exposure. We cannot promise any benefits to others from participation in this research. However, the information we gain from this study could help future healthcare workers and high-risk people who have been exposed to COVID-19.

- **Alternatives.** The alternative to this study is to not participate. Whether or not you choose to take part, your medical care will continue as planned by your physician.

What will happen during this study?

We are asking you to participate in this research study because you are 1) a healthcare worker and have had a positive exposure to COVID-19 in the workplace or in the community or; 2) you are considered a high-risk individual who has had a positive exposure to COVID-19. Each of these groups are called cohorts.

Before signing this document, study staff will review this consent form and study details with you and answer any questions you may have about the study. If you choose to participate and sign the informed consent form, the study team will collect some basic information about your health and any medications you might be taking. If the study team determines that you meet all of the criteria for participation in this study, you will be enrolled and randomly assigned to receive hydroxychloroquine or placebo. The treatment you get will be chosen by chance, like flipping a coin. You will have an equal chance of getting either treatment. Neither you nor the study team will know if you are receiving hydroxycholoroquine or Vitamin D with calcium (placebo).

The two treatment groups are as follows:

Control Group:	You will receive 5 days of Vitamin D with calcium, along with instructions for dosing and a pill diary.
Treatment Group:	You will receive 5 days of hydroxychloroquine along with instructions for dosing and a pill diary.

Both the Control Group and the Treatment Group will complete a pill diary to confirm that you took the study medication correctly. Both groups will also receive follow-up phone calls from the study team on days 3, 5, 14, 35 and 12 months to see if you have any symptoms of or have tested positive for COVID-19, or if you've had any side effects from the medication.

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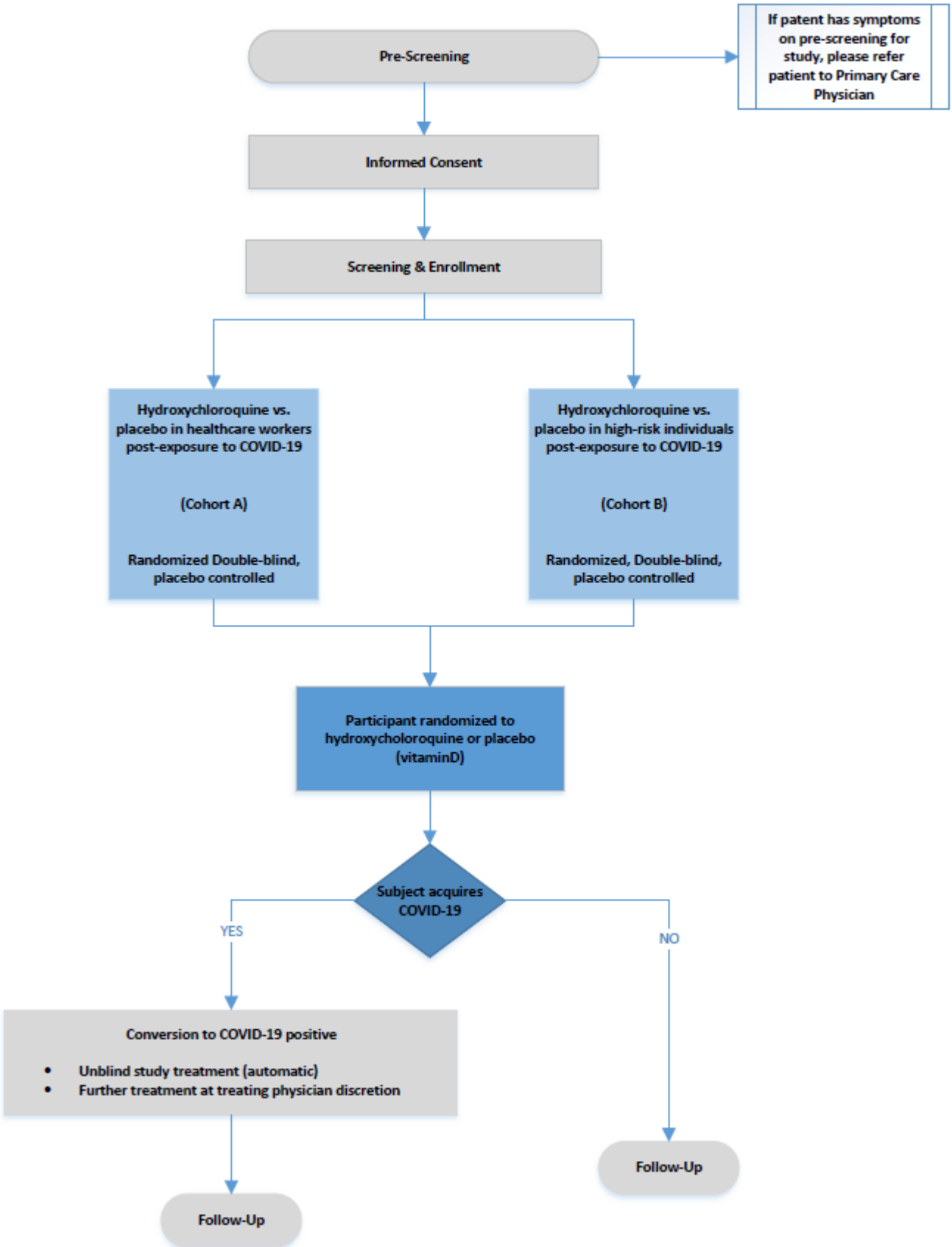
Trial Schema



ADDITIONAL INFORMATION

There are potential risks in this research study with both hydroxychloroquine and Vitamin D with calcium. The study team will review your medical history and medications to make sure that you are not at an increased risk.

Hydroxychloroquine: There are known risks with hydroxychloroquine. Common side effects may include nausea, vomiting, diarrhea and loss of appetite. Rarely, other more severe side effects are seen.

- Retinopathy (vision damage)- irreversible retinal damage has been seen in some patients, however this is seen most often in patients who have taken hydroxychloroquine for at least 5 years.
- Cardiac (heart) Effects Cardiomyopathy and QT Prolongation- Cardiomyopathy is a disease of the heart muscle that makes it harder for your heart to pump blood. There have been cases of life-threatening and fatal cardiomyopathy with use of hydroxychloroquine. QT prolongation is a heart rhythm condition that can potentially cause fast, chaotic heartbeats. Certain medical conditions and medications increase your risk of these cardiac side effects. Your health history will be thoroughly reviewed to make sure you are not at an increased risk. If you notice your heart beating irregularly, it is important to contact your doctor or call 911 if it is an emergency.
- Myopathy (muscle damage) and Neuropathy (nerve damage)- muscle and nerve damage leading to weakness and wasting away of muscle groups has been reported.
- Suicidal behavior has been rarely reported in patients treated with hydroxychloroquine
- Hypoglycemia (low blood sugar)- hydroxychloroquine has been shown to cause severe hypoglycemia including loss of consciousness that could be life threatening in patients treated with or without diabetes medications.
- Dermatologic (skin) Effects- skin reactions to hydroxychloroquine may occur.
- If you are pregnant, this treatment may hurt your baby or your pregnancy in ways that are unknown. You will not be allowed to take this drug if you are pregnant. You will be responsible for using effective birth control methods during the treatment phase of this trial.

Vitamin D with calcium (Placebo): While Vitamin D with calcium is a common supplement, there are some risks with the medication. The amount of calcium in 5 days of the Vitamin D is the equivalent of taking 1/2 of a standard calcium tablet and should pose no additional risk.

- **Renal (Kidney)-** Decreased kidney function including excessive amount of urination, having to urinate at night, and increased calcium and nitrogen compounds in the urine.
- **Central Nervous System** - mental retardation, disorientation and confusion
- **Soft Tissues**- calcification (hardening) of tissues including the heart, blood vessels, kidney tubules and lungs
- **Skeletal**- osteoporosis (brittle fragile bones) in adults, vague aches, stiffness and weakness
- **Gastrointestinal (stomach and intestines)**- nausea, weight loss and constipation
- **Metabolic**- mild acidosis (excessive acid in the body), anemia and weight loss
- **Pregnancy**- heart defects, facial deformities and mental retardation have been recorded in pregnant women taking excessive amounts of Vitamin D

Confidentiality and Privacy

While we cannot guarantee absolute confidentiality, we will use all available security measures to minimize the risk that this information would be given to someone outside of the study. Your study record may be reviewed by or disclosed to other researchers, the Sanford Institutional Review Board (IRB), Sanford Research Compliance, and the Food and Drug Administration (FDA).

Researchers would like to use your health information for research. This information includes data that identifies you. If you agree to this research, you give permission to the research team to use or disclose (release) your health information that identifies you.

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record. If you are receiving care or have received care at Sanford (outpatient or inpatient) and are participating in a Sanford research study, results of research-related procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by Sanford.

By agreeing to this research, you authorize Sanford Health to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. This authorization expires at the end of the research study.

You do not have to agree to this authorization, but if you do not, you may not participate in this study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

You may be withdrawn at any time at the discretion of the principal investigator for safety, behavioral, compliance, or administrative reasons. Data that has already been collected will be kept and used for analysis.

If you wish to discontinue study medication or withdraw from the study prior to completing the 5 day course, please contact the study team. Data that has been already been collected will be kept and used for analysis, but no further information will be collected. Also, even if you revoke your authorization, health information already obtained about you may be used or disclosed as necessary to maintain the integrity or reliability of the current research. To withdraw from this research study or revoke authorization to use or disclose your health information, you must contact the study team in writing at the below address:

Susan Hoover, MD, PhD
Attn: SH HCQ Trial
Sanford Research
2301 E. 60th Street North
Sioux Falls, SD 57104-0569

We may publish the results of this research. However, we will keep your name and other identifying information confidential. You will be informed by the research investigator[s] of this study about any significant new findings that develop during the study which may influence your willingness to stay in the research. If the research with your identifiable information gives results that have meaning for your health, the researchers will contact you to let you know what they have found. The information collected for this study might be de-identified (identifiers removed, such as name, address, and date of birth) and used for future research search studies or distributed to another investigator for future research studies without your additional informed consent.

Who is funding this study?
This study is funded by the state of South Dakota and Sanford Health.

Will it cost me anything to be in this study?
You will not have additional costs for being in this study. You and your insurance company will be charged for the health care services for which you would ordinarily be responsible to pay.

What if I am injured as a result of this study?
All research involves some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the investigator and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care will be sought first from your insurer, managed care plan, or other benefits program. You will be responsible for any associated co-payment or deductible as required by your insurance. If costs of care related to such an injury are not covered by your insurer, managed care plan, or other benefits program, you may be responsible for these costs. There are no plans to compensate you for a research related injury or illness.

You do not waive any liability rights for personal injury by signing this form.

Will I be paid for participating in this study?
You will not be paid for being in this research study.

Email Communication
We would like your permission to email you so we can contact you about involvement in future COVID-19 related studies. Email is generally not a secure way to communicate, as there are ways for unauthorized users to access the communication. Email should not be used to convey information of an urgent nature. If you agree to provide and allow use of email, it would be limited to this study. We will never ask you to provide sensitive information like your Social Security number over email. You do not have to provide your email address to participate in this study.

___ Yes, the study team may use email to communicate with me for this study.

Email Address _____

___ No, I do not want the study team to communicate with me by email.

Physician Contact

We would like your permission to contact your primary care provider to let them know that you are participating in this trial.

____ Yes, the study team may contact my primary care provider

Name of Provider _____

Facility _____

____ No, the study team may not contact my primary care provider

____ I do not have a primary care provider

If you have side effects related to the trial, contact your primary care physician. In the event of a medical emergency dial 911 or go to your nearest emergency department.

Who can I talk to?
You may ask any questions you have now or later. If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 605-328-1368.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). An Institutional Review Board is a group of people who protect the rights and welfare of people who participate in research. You may talk to them at (605) 312-6430 to discuss your rights while in this study, discuss problems, and to ask questions, offer input, or talk to someone besides the research team.

For this study you must be 18 years of age older to consent to participate in this research study.

Your signature documents your consent to take part in this research.

_____ _____/_____/_____
Signature of Participant Day Month Year

_____
Printed Name of Participant